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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/151,612	09/11/98	KOHN	L 5616/3

HM12/1230

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EXAMINER	
BECKERLEG, A	
ART UNIT	**PAPER NUMBER**
1632	7

DATE MAILED: 12/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/151,612	Applicant(s) Kohn et al.
	Examiner Anne Marie S. Beckerleg	Group Art Unit 1632

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-75* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-75* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-35, 42-46, 60-66, and 74-75 drawn to methods of increasing the expression of an immune recognition molecule, methods of increasing antigen presentation, and methods of treating mammalian disease comprising introducing double-stranded polynucleotides into cells, classified in classes 435, 424 and 514, subclasses 325, 93.2 and 44 respectively.

II. Claims 36-39, drawn to methods of drug screening, classified in class 435 , subclass 4.

III. Claim 40, drawn to pharmaceutical compositions comprising a drug, classified in class 424, subclass 900.

IV. Claim 41, drawn to DNA molecules , classified in class 536, subclass 23.1.

V. Claims 47-56, drawn to methods of identifying differential expression of a sequence comprising isolating and comparing RNA sequences, classified in class 435, subclass 6.

VI. Claims 57-59, drawn to methods of screening for a compound that regulates the in vivo effects of double-stranded polynucleotides, classified in classes 424 and 435, subclasses 9.2 and 4.

VII. Claims 67-73, drawn to methods to assess viral replication comprising measuring

levels of gene expression, classified in class 435, subclass 6.

The inventions are distinct each from the other for the following reasons:

1. Invention I is distinct from inventions II, III, and VI in that the methods of drug screening and compound screening of inventions II and VI, and the pharmaceutical compositions comprising a drug involve the administration of drugs or compounds which are significantly different in structure, properties, and function from the double-stranded polynucleotides of invention II.

2. Invention I is distinct from invention IV in that the DNA molecules of invention IV can be used for substantially different purposes than the methods of increasing antigen presentation or methods of treating disease, such as the use of the DNA molecules in *in vitro* hybridization assays or to make probes useful for PCR.

3. Invention I is distinct from inventions V and VII in that the methods of invention V utilize *in vitro* RNA isolation and use of said RNA in *in vitro* assays which are differ substantially in activity from *in vivo* methods of increasing antigen presentation or immune response recognition molecule expression, and that the methods of assessing viral replication involve infecting cells with viruses which are substantially different in structure, properties, and activity from double-stranded polynucleotides.

4. Invention II is distinct from invention III in that drugs of invention III are for *in vivo* administration and are required to elicit a therapeutic response in the host whereas the methods of drug screening of invention II are performed *in vitro* and thus occur under substantially different conditions than those in a mammal.

5. Inventions II and III are distinct from invention IV, V, and VII in that the drugs of inventions II and III are substantially different in structure, properties, and activity from the DNA molecules, double-stranded polynucleotides, and viruses of inventions IV, V and VII.

6. Invention II is distinct from invention VI in that the screening methods of invention II are performed *in vitro* and thus occur under substantially different conditions than those of invention VI which are performed *in vivo*.

7. Invention III is distinct from invention VI in that the compounds of invention VI are not required in and of themselves to have a therapeutic effect on any condition, but rather are administered to modify the effects of cells have been modified to express double-stranded polynucleotides.

8. Invention IV is distinct from inventions V-VII in that the DNA molecules of invention IV can be used for substantially different purposes than the methods of assessing viral replication, methods of screening for a compound, or methods of identifying differential gene expression, such as the use of the DNA molecules in *in vitro* hybridization assays or to make probes useful for PCR.

9. Inventions V-VII are distinct in that the methods of screening a compound *in vivo* are substantially different from methods of identifying differential expression or viral replication *in vitro* which do not utilize said compound, further the methods of identifying differential expression involve the use of *in vitro* RNA assays, whereas the methods of assessing viral replication involve the infection of cells *in vitro* with virus.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and requirement for different searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 8:30-6:00. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The official fax number is (703) 308-4242.

Dr. A.M.S. Beckerleg

Bruce Campell

BRUCE R. CAMPELL
PRIMARY EXAMINER
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